Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

In its analysis, ICIS notes that the 28 August agreement indicates that SK Capital will be paying $2.35 per share for the initial 40% block of shares in Venator, purchased from Huntsman. The option for the residual 9% block owned by Huntsman is priced at $2.15 per share. Initially, news of this deal lifted Venator's share price from $1.80 at the close of trading on 26 August to $2.30, but it then fell back below the $2 level. According to ICIS, SK Capital may well proceed with a full takeover for Venator. Other bidders would probably include Ineos, Lomon Billions and Tronox.

Original Source: ICIS Chemical Business, 4-10 Sep 2020, 298 (9), 7 (Website: http://www.icis.com) (Reed Business Information Limited 2020. Original Source: Venator Materials, 20 Sep 2020 (Titanium House, Hanzard Drive, Wynyard Park, Stockton-on-Tees TS22 5FD, UK. Website: http://www.venatorcorp.com). © Venator 2020.

LITIGATION

Allele alleges unlicensed use of its *mNeonGreen* by Pfizer, BioNTech & Regeneron

News about potentially effective therapies and vaccines designed to treat or protect against infections by the *Covid-19* virus has featured strongly in popular as well as scientific literature in recent months.

Regeneron Pharmaceuticals (headquartered in Tarrytown, NY) hit the headlines in early October 2020 when US President Trump attributed his swift recovery from a *Covid-19* infection to treatment with *Regn-Cov2*, the antibody cocktail supplied by Regeneron. Commenting on 29 September on the results from initial clinical trials with 275 patients with laboratory confirmed cases of *Covid-19*, Dr George Yancopoulos (President & Chief Scientific Officer stated: "We are extremely gratified to see that *Regn-Cov2* rapidly reduced viral load and associated symptoms in infected patients. The greatest treatment benefit was in patients who had not mounted their own effective immune response, suggesting that *Regn-Cov2* could provide a therapeutic substitute for the naturally-occurring immune response. These patients were less likely to clear the virus on their own, and they were at greater risk for prolonged symptoms."

On 9 November 2020, Pfizer Inc (headquartered in New York) and BioNTech (headquartered in Mainz, Germany) declared the results of their *Phase 3* clinical trial of their jointly developed *BNT-162-b2* vaccine, showing that it was more than 90% effective in preventing *Covid-19* infection in study participants who had no evidence of prior infection. Nine days later, after further analysis, Pfizer and BioNTech raised their estimate of the vaccine's efficacy rate to 95%. They also noted that the vaccine efficacy rate exceeded 94% for adults over the age of 65. Dr Albert Bourla (Chairman & CEO of Pfizer) said: "Today is a great day for science and humanity. We are reaching this critical milestone in our vaccine development programme at a time when the world needs it most, with infection rates setting new records, hospitals nearing over-capacity and economies struggling to reopen. Now, we are a significant step closer to providing people around the world with a much-needed breakthrough to help bring an end to this global health crisis." Prof Ugur Sahin (of BioNTech) said: "When we embarked on this journey ten months ago, this is what we aspired to achieve. Especially today, while we are all in the midst of a second wave and many of us are in Lockdowns, we appreciate even more how important this milestone is on our path towards ending this pandemic, so that all of us can regain a sense of normality."

However, all three companies have been named as defendants in patent infringement lawsuits filed by Allele Biotechnology & Pharmaceuticals Inc (headquartered in San Diego, CA) centred on the unauthorised and unlicensed use of *mNeonGreen*. On 6 October 2020, Allele Biotech filed a lawsuit against Regeneron in the Southern District Court of New York (Case reference 7:20-cv-08255). On the same day, the company filed a lawsuit against Pfizer, BioNTech SE and its US subsidiary (Case reference 3:20-cv-01958-GPC-AHG).

Allele Biotech was granted *US Patent 10,221,221B2* on 5 March 2019, having initially filed its patent application on 24 July 2013. The inventors were named as Nathan Shaner, Gerard Lambert, Yuhui Ni and Jiwu Wang. The patent describes a method for engineering isolated nucleic acid sequences that encode for monomeric green-yellow fluorescent proteins. The patent also covers the generation of an antibody that specifically binds to the green-yellow fluorescent protein. Allele Biotech has commercialised its technology with the development of *mNeonGreen* – the brightest known monomeric fluorescent protein – marketed as a biomarker and/or protein fusion tag. It is said to be the "gold standard" reagent for use in assays testing neutralising antibody and vaccine candidates. It is alleged that Regeneron, Pfizer and BioNTech have been using *mNeonGreen* in their commercial assays without authorisation from Allele Biotech.

Dr Jiwu Wang (CEO of Allele Biotech) commented: "I am pleased that *mNeonGreen* has played a pivotal role in the fight against *Covid-19*. In no way does Allele want to prohibit or slow down the development of vaccines or therapeutics discovered using this technology. But our goal (when filing these patent infringement lawsuits) is to have these companies respect our intellectual property and recognise the hard work that went into developing this technology." Hundreds of organisations and universities already have active licences to use Allele's *mNeonGreen* technology.

Allele Biotech is not seeking equitable relief or an injunction, which would stop any of the three companies using *mNeonGreen*. But it is seeking the payment of compensatory damages.

Possibly the defendants may try to claim immunity from patent infringement under the *Public Readiness & Emergency Preparedness (PREP) Act*, which was signed into law by President George W. Bush in December 2005. The *PREP Act* provides a tort liability shield giving companies immunity from potential financial liability for clinical trials of vaccine that effectively had been accelerated under orders or exhortations from the Government. Back in 2004/05, the immediate threat was an uncontrolled outbreak of "bird flu" – a human influenza caused by the zoonotic *H5N1* virus. Vaccine manufacturers had lobbied strongly for this kind of legislation, which would effectively pre-empt individual State vaccine safety laws in the case of an emergency declaration by the US Department of Health & Human Services. At that time, many pharmaceutical companies declared that they would not try to develop or produce new vaccines unless they had a tort liability shield.

Original Source: Allele Biotechnology & Pharmaceuticals Inc, 6 Oct 2020 (6404 Nancy Ridge Dr, San Diego, CA 92121, USA. Website: http://www.allelebiotech.com) © Allele Biotech 2020. Original Source: Regeneron Pharmaceuticals Inc, 29 Sep 2020 (777 Old Saw Mill River Road, Tarrytown, NY 10591, USA. Website: http://www.regeneron.com) © Regeneron 2020. Original Source: Pfizer Inc, 9 & 18 November 2020 (235 East 42nd Street, New York, NY 10017, USA. Website: http://www.pfizer.com) © Pfizer 2020. Original Source: JOLT Digest, 20 Oct 2020 (Harvard Law School, Suite 350, Wasserstein Hall, 1585 Massachusetts Avenue, Cambridge, MA 02138, USA. Website: http://www.jolt.law.harvard.edu) © Harvard Journal of Law and Technology 2020.